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Effects of tetrodotoxin on cue-induced drug craving in abstinent heroin addicts

Submission date	Recruitment status	[ ] Prospectively registered
18/06/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/06/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
123456

Study information

Scientific Title
Effects of tetrodotoxin on cue-induced drug craving in abstinent heroin addicts

Study objectives
The purpose of this double-blind placebo-controlled study was to assess the effect of a single intramuscular dose of tetrodotoxin (TTX) on cue-induced craving and anxiety in abstinent heroin addicts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Human Investigation Committee of the Peking University Health Centre on the 27th June 2007 (ref: 21).

Study design
Double blind placebo-controlled, between-subjects design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Addiction

Interventions
The abstinent heroin addicts were randomly assigned to three treatment groups:
1. Placebo
2. 5 µg tetrodotoxin
3. 10 µg tetrodotoxin
Each treatment was administered once only, intramuscularly, before exposure to a neutral video or a heroin-related video. Craving, anxiety, blood pressure, and heart rate were measured pre- and post-exposure.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Tetrodotoxin

Primary outcome measure
Cue-induced craving and anxiety.

Both the primary and secondary outcomes were measured at 0 minutes (baseline, before TTX administration), 60 minutes (1 hour after TTX administration), 65 minutes (immediately after the first video presentation), 75 minutes (before the second video presentation), and 80 minutes (immediately after the second video presentation).

Secondary outcome measures
Heart rate and blood pressure.

Both the primary and secondary outcomes were measured at 0 minutes (baseline, before TTX administration), 60 minutes (1 hour after TTX administration), 65 minutes (immediately after the first video presentation), 75 minutes (before the second video presentation), and 80 minutes (immediately after the second video presentation).

Overall study start date
08/02/2008

Completion date
20/03/2008

Eligibility

Key inclusion criteria
1. Men or non-pregnant/nursing women 18 - 45 years old
2. Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM- IV) criteria for heroin dependence, but opiate-free for at least one month
3. No use of cocaine and other drugs

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Forty-five participants

Total final enrolment
45

Key exclusion criteria
1. Current or past cardiovascular disease
2. History of allergy (food, medicine)
3. Current or past psychiatric illness
4. Neurological signs and/or history of neurological disease
5. Current medical illness
6. Participation in other clinical trials of medications within the past three month

Date of first enrolment
08/02/2008

Date of final enrolment
20/03/2008

Locations

Countries of recruitment
China

Study participating centre
National Institute on Drug Dependence
Beijing
China
100083

Sponsor information

Organisation
The National Basic Research Program of China (973 Program) (China)

Sponsor details
-
Bejing
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jcc973@vip.sina.com

Sponsor type
Government

Website

http://www.973.gov.cn/

ROR
https://ror.org/027s68j25

Funder(s)

Funder type
Government

Funder Name
The National Basic Research Program of China (973 Program) (China) (ref: 2007CB512302)

Funder Name
The National High Technology Research and Development Program of China (863 Program) (China) (ref: 2006AA02Z4D1)

Funder Name
The China-Canada Joint Health Research Program (China) (ref: 30611120528)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2009	04/06/2019	Yes	No